

The Commonwealth of Massachusetts Executive Office of Health and Human Services Department of Public Health 250 Washington Street, Boston, MA 02108-4619

Board of Registration in Pharmacy Drug Control Program Immunization Program

MARYLOU SUDDERS Secretary

MARGRET R. COOKE Commissioner

Tel: 617-624-6000 www.mass.gov/dph

Policy 2022-05: COVID-19 Vaccine and EVUSHELD™ Administration by Qualified Pharmacy Personnel

The Massachusetts Department of Public Health ("DPH or the Department"), through the Board of Registration in Pharmacy ("Board"), Drug Control Program ("DCP"), and Immunization Program jointly authorize the administration of any FDA-approved, authorized, cleared, or licensed COVID-19 vaccines and EVUSHELD™ in accordance with the Secretary of Health and Human Services' Declaration under the PREP Act.

Although qualified pharmacy personnel are authorized to administer COVID-19 vaccines and EVUSHELD™, refer to specific manufacturer information, Food and Drug Administration ("FDA"), and Centers for Disease Control and Prevention ("CDC") guidelines for approved age groups.

Pharmacists may order and administer, and pharmacy interns and qualified pharmacy technicians may administer any FDA-approved, authorized, cleared, or licensed **COVID-19 vaccines** to populations authorized by the FDA and CDC, and in accordance with this policy, to persons aged 3 years and above. Additionally, pharmacists and pharmacy interns may also administer investigational vaccines for COVID-19 as part of clinical trials in accordance with this policy.

Pharmacists, pharmacy interns and qualified pharmacy technicians may administer the COVID-19 therapeutic EVUSHELD™ (tixagevimab co-packaged with cilgavimab) to populations authorized by the FDA and CDC and in accordance with this policy.

Please note carefully, certain allowances and requirements of this policy will terminate when the emergency declaration under the PREP Act terminates. After termination, policy details will be reevaluated.

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I. COVID-19 Vaccines

- A. In order to administer FDA-approved, authorized, cleared, or licensed COVID-19 vaccines, pharmacists and pharmacy interns must comply with all requirements listed in <u>Policy 2020-11: Vaccine Administration</u> and <u>105 CMR 700.004(B)(6)</u>.
- B. In order to administer FDA-approved, authorized, cleared, or licensed COVID-19 vaccines, qualified pharmacy technicians must comply with all requirements listed in Policy 2020-12: Vaccine Administration by Qualified Pharmacy Technicians.
- C. Pharmacists must generate a patient-specific prescription prior to administration. Pharmacists may only order an eligible product in accordance with manufacturer approved labeling for the specific product to be administered.

D. Investigational vaccine trials:

- a. The researcher responsible for the study must have or obtain a Researcher Massachusetts Controlled Substance Registration ("Researcher MCSR") from DCP that specifically indicates pharmacists and pharmacy interns may administer the investigational vaccine as part of the research activity authorized by the Researcher MCSR.
- b. The pharmacist and pharmacy intern must comply with all applicable requirements listed in <u>Policy 2020-11: Vaccine Administration</u> and <u>105 CMR</u> 700.004(B)(6).
- c. If a Board licensed pharmacy is to be involved with an investigational vaccine trial:
 - i. they must follow the requirements of <u>Policy 2018-06: Retail Pharmacy</u> *Participation in Research Drug Studies*;
 - ii. the researcher must obtain a separate Researcher MCSR for each pharmacy site where the investigational vaccine will be stored; and
 - iii. investigational vaccines must be stored in accordance with manufacturer recommendations and / or study protocol.

II. EVUSHELD™ (tixagevimab co-packaged with cilgavimab)

A. Training

Pharmacists, pharmacy interns, and qualified pharmacy technicians must complete ACPE-approved training that includes:

- a. immunization training requirements as outlined above in section I: COVID-19 Vaccines to include competency in intramuscular gluteal administration;
- b. clinical evaluation of indications and contraindications of EVUSHELD™;

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- c. recognition and treatment of emergency reactions to EVUSHELD™; and
- d. any additional training required in the FDA Emergency Use Authorization ("EUA").

B. Administering

Pharmacists, pharmacy interns, and qualified pharmacy technicians may administer EVUSHELD™ when the following criteria are met:

- a. intramuscular administration, in accordance with the EUA;
- b. compliance with any state or federal requirements, including recordkeeping, adverse event reporting and informing the patient's primary-care provider when available:
- c. compliance with any applicable conditions of use that may apply (e.g., pregnancy screening);
- d. appropriate private space (e.g., counseling / immunization room) based on the nature of administration (i.e., gluteal injection); and
- e. clinical monitoring and observation of individuals for 1 hour after the injections, in accordance with the EUA.

Supersedes Policy 2020-13

Please direct any questions to: Pharmacy.Admin@mass.gov

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